

Assembly Bill No. 2682

Passed the Assembly August 27, 2004

Chief Clerk of the Assembly

Passed the Senate August 27, 2004

Secretary of the Senate

This bill was received by the Governor this _____ day of
_____, 2004, at _____ o'clock __M.

Private Secretary of the Governor

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CHAPTER _____

An act to amend, repeal, and add Section 4043 of, to add and repeal Section 4162.5 of, and to repeal and add Section 4161 of, the Business and Professions Code, relating to pharmacy, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 2682, Negrete McLeod. Pharmacy: out-of-state wholesalers.

The Pharmacy Act provides for licensing and regulation of manufacturers and wholesalers of prescription drugs and devices by the California State Board of Pharmacy and makes a violation of its provisions a crime. Existing law requires out-of-state manufacturers and wholesalers of prescription drugs and devices selling or distributing those drugs and devices in this state to obtain an out-of-state dangerous drugs and devices distributor's license from the board, unless they sell or distribute only through a licensed wholesaler.

This bill would delete these requirements applicable to out-of-state manufacturers and wholesalers of prescription drugs and devices on January 1, 2006. The bill would instead, on and after January 1, 2006, require a nonresident wholesaler, as defined, that ships, mails, or delivers dangerous drugs or dangerous devices in this state to obtain a nonresident wholesaler's license from the board. The bill would, on and after January 1, 2006, require, until January 1, 2011, a nonresident wholesaler to submit a surety bond of \$100,000, or an equivalent means of security for each place of business owned or operated by the nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in California. Because this bill would require additional persons to pay fees to the board to obtain a license, it would result in the deposit of additional revenue in the Pharmacy Board Contingent Fund, a continuously appropriated fund, and would thereby make an appropriation.

Because a violation of the Pharmacy Act is a crime, the bill would impose a state-mandated local program by revising the definition of a crime.



The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

This bill would become operative only if SB 1307 is also enacted and becomes effective on or before January 1, 2005.

Appropriation: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4043 of the Business and Professions Code is amended to read:

4043. (a) “Wholesaler” means and includes every person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or out-of-state distributor, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.

(b) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

SEC. 2. Section 4043 is added to the Business and Professions Code, to read:

4043. (a) “Wholesaler” means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.

(b) This section shall become operative January 1, 2006.

SEC. 3. Section 4161 of the Business and Professions Code is repealed.

SEC. 4. Section 4161 is added to the Business and Professions Code, to read:



4161. (a) A person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state at wholesale shall be considered an out-of-state distributor.

(b) An out-of-state distributor shall be licensed by the board prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.

(c) A separate license shall be required for each place of business owned or operated by an out-of-state distributor from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in this state. A license shall be renewed annually and shall not be transferable.

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of an out-of-state distributor license, or within 30 days of a change in the following information:

(1) Its agent for service of process in this state.

(2) Its principal corporate officers, as specified by the board, if any.

(3) Its general partners, as specified by the board, if any.

(4) Its owners, if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) An out-of-state distributor shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.

(g) An out-of-state distributor wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.

(h) An out-of-state distributor shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for an out-of-state distributor license in this state shall include a license verification from the licensing authority in the applicant's state of residence.

(i) The board may not issue or renew an out-of-state distributor license until the out-of-state distributor identifies an

exemptee-in-charge and notifies the board in writing of the identity and license number of the exemptee-in-charge.

(j) The exemptee-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be the exemptee-in-charge.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as an out-of-state distributor.

(l) The license fee shall be the fee specified in subdivision (f) of Section 4400.

(m) A pharmacy that meets the requirements of Section 4001.2, as added by Senate Bill 1149 of the 2003–04 Regular Session, including any subsequent amendment thereto, shall not be considered an out-of-state distributor for purposes of this section.

(n) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

SEC. 4.5. Section 4161 is added to the Business and Professions Code, to read:

4161. (a) A person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.

(b) A nonresident wholesaler shall be licensed by the board prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.

(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in this state. A license shall be renewed annually and shall not be transferable.

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in that information:



- (1) Its agent for service of process in this state.
- (2) Its principal corporate officers, as specified by the board, if any.
- (3) Its general partners, as specified by the board, if any.
- (4) Its owners if the applicant is not a corporation or partnership.
- (e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.
- (f) A nonresident wholesaler shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.
- (g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.
- (h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.
- (i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.
- (j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.
- (k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a nonresident wholesaler.



(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

(m) A pharmacy that meets the requirements of Section 4001.2, as added by Senate Bill 1149 of the 2003–04 Regular Session, including any subsequent amendment thereto, shall not be considered a nonresident wholesaler for purposes of this section.

(n) This section shall become operative January 1, 2006.

SEC. 5. Section 4162.5 is added to the Business and Professions Code, to read:

4162.5. (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars (\$100,000) for each site to be licensed, or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purpose of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars (\$100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten million dollars (\$10,000,000) or less in which the surety bond shall be twenty-five thousand dollars (\$25,000).

(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars (\$100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, 2011, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends those dates.



SEC. 6. This act shall become operative only if Senate Bill 1307 is also enacted and becomes effective on or before January 1, 2005.

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.



Approved _____, 2004

Governor

